REMARKS

A check for the fee for a one-month extension of time accompanies this response. Any fees that may be due in connection with filing this paper or with this application may be charged to Deposit Account No. 50-1213. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 1-8, 11-20, 44-53, 69-71 and 75 are pending in this application. Claims 6, 11, 15, 47 and 69 are amended to more particularly point out and distinctly claim the subject matter. For example, claim 11 has been amended to indicate that the claimed primers, probes or antisense nucleic acid molecules hybridize to the reference sequence under high stringency conditions. Basis for the amendments can be found, for example, at page 30; and at page 39, lines 10-11. The specification is amended to correct a typographical error regarding the year of publication. No new matter has been added.

OATH/DECLARATION:

A new Declaration For Patent Application claiming benefit under 35 U.S.C. §119(e) was submitted under separate cover on June 6, 2003.

PRIORITY CLAIM:

Applicant respectfully disagrees with the Examiner's assertion that:

> The instant specification contains a large paragraph discussing related applications, however never specifically asserts whether priority is being claimed.

The first sentence in the specification as filed reads as follows:

> **Benefit of priority under 35 U.S.C. §119(e)** to U.S. provisional application Serial No. 60/217,251, filed July 10, 2000, to Andreas Braun, entitled "POLYMORPHIC KINASE ANCHOR PROTEINS AND NUCLEIC ACIDS ENCODING THE SAME" **is claimed herein. Benefit of priority under 35 U.S.C. §119(e)** to U.S. provisional application Serial No. 60/240,335, filed October 13, 2000, to Andreas Braun, entitled "POLYMORPHIC KINASE ANCHOR PROTEINS AND NUCLEIC ACIDS ENCODING THE SAME" **also is claimed herein.** (emphasis added)

Contrary to the Examiner's assertion, the benefit of priority is explicitly claimed under 35 U.S.C. §119(e) to U.S. provisional application Serial No. 60/217,251, filed July 10, 2000; and to U.S. provisional application Serial No. 60/240,335, filed October 13, 2000. The second paragraph of the specification contains related applications, for which no priority is claimed.

SPECIFICATION INFORMALITIES:

The specification, at page 99, line 2, has been amended to replace the obviously incorrect year "1007" with "1997."

THE REJECTION OF CLAIMS 1-8, 11-20, 44-53, 69-71 and 75 UNDER 35 U.S.C. §101; AND 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1-8, 11-20, 44-53, 69-71 and 75 are rejected under 35 U.S.C. §101, as allegedly not supported by a substantial asserted utility or a well established utility. This rejection is respectfully traversed.

RELEVANT LAW

It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (*e.g.*, a machine, an article of manufacture or a composition of matter). Regardless of the category of invention that is claimed (*e.g.*, product or process), an applicant need only make one credible assertion of specific utility to satisfy 35 U.S.C. §101 and 35 U.S.C. §112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. See, *e.g.*, *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown."); *In re Gottlieb*, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful."); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. &

Inter. 1988). Thus, if applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established.

> The MPEP provides further guidance to its office personnel that:
>
> Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations in other cases to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. See, *e.g.*, *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966). **Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a "substantial" utility.**

In addition, rejections under 35 U.S.C. §101 rarely have been sustained by federal courts. Generally speaking, in these rare cases, the 35 U.S.C. §101 rejection was sustained either because the applicant failed to disclose any utility or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967).

ANALYSIS

As set forth above, patent specifications rarely possess or assert a single utility. The MPEP §2107 "GUIDELINES FOR EXAMINATION OF APPLICATIONS FOR COMPLIANCE WITH THE UTILITY REQUIREMENT" states, at §2107 II.(B)(1)(ii), that:

> An applicant need only provide **one credible assertion of specific and substantial utility for each claimed invention** to satisfy the utility requirement.

In addition, MPEP §2107 II.(A)(3), states that:

> If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would

> immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

Regarding the utility of screening assays as research tools, MPEP §2107.01 I. states:

> **Research Tools**
> Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, **screening assays**, and nucleotide sequencing techniques **have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.** Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

Thus, the MPEP clearly acknowledges that screening assays that are useful in analyzing compounds **"have a clear, specific and unquestionable utility."**

Regarding the nucleic acid molecules of claims 1-8, 19-20, 44-46 and 51-53, the specification, at the paragraph bridging pages 20 and 21, teaches that:

> Methods are also provided for indicating or predicting an alteration in signal transduction in an organism. Furthermore, AKAP10-5 and other allelic variants of the AKAP10 gene **are potential functional variants of...a gene related to an alteration in signal transduction and associated disorders and thus may also be useful for screening for potential therapeutics.**

In addition, the specification, at pages 40-41, teaches that:

> Polymorphisms of the genome can lead to altered gene function, protein function or mRNA instability. AKAPs provide a mechanism for regulating ubiquitous cAMP-dependent kinase (PKA) activity by tethering PKA to specific subcellular locations thereby segregating it with particular components in a given signaling pathway and contributing to specificity in cellular responses to extracellular signals. AKAPs thus play a fundamental role in the basic functioning of cells, the response of cells to their environment and ultimately in the coordination of vital systems within an organism. Therefore, polymorphisms in AKAP gene sequences may significantly affect the proper functioning of cells and systems within organisms and could be directly linked with certain disorders or could predispose an organism to a variety of diseases and disorders, **especially those involving alterations in cellular protein phosphorylation and/or signal transduction. Among such disorders and diseases are: neurodegeneratives diseases, such as Alzheimer's Disease, cardiovascular disorders, cardiac disorders, particularly disorders associated with altered left ventricular function, cardiomyopathies, proliferative disorders, bipolar disorder and other neurological disorders, obesity, diabetes and certain peripheral retinopathies, such as retinitis pigmentosa. The discovery of AKAP gene polymorphisms, such as those described herein, provides for the identification and development of diagnostic and prognostic methods, also provided herein, and the development of drug therapies and treatment regimens.**

Thus, the claimed nucleic acids also are useful in screening assays to identify compounds that modulate altered signal transduction. The alteration in signal transduction biological activity is reasonably correlated to specific diseases, such as diabetes, cardiomyopathies, and the like. Thus, because the specification teaches that the claimed nucleic acids are useful in screening assays to identify compounds that modulate signal transduction and reasonably correlates altered signal transduction activity to specific diseases, it is respectfully submitted that the screening assays set forth in the specification, that are useful in analyzing compounds **"have a clear, specific and unquestionable utility."**

Moreover, the specification, at page 90, teaches that:

> J. **Screening assays for modulators**
>
> Modulators of AKAP10 biological activities may be identified by using any of the disclosed methods related to AKAP10 binding to PKA, AKAP10 localization in the mitochondria, binding to other signaling enzymes and phosphorylation by PKA.
>
> **In particular, once a variant protein such as AKAP10-5 is contacted with a potential modulating molecule the effect of the molecule on the binding between AKAP protein and PKA can be determined by using the assays disclosed in the section entitled " Effect of Allelic Variants".** For example mitochondria can be isolated from cells exposed to the potential modulating molecule. PKA protein can then be isolated and quantitated or phosphorylation can be determined using the disclosed PKA assay. An increase in the amount of PKA protein in the mitochondria or the quantity of test peptide phosphorylated by mitochondrial isolated PKA would indicate a positive effect of the test molecule. Binding of AKAP10 protein and PKA could be directly assessed using an in vitro binding assay, or other disclosed binding assays, or by immunoassays such as immunoprecipitation.

Thus, the claimed nucleic acids also are useful in screening assays to identify compounds that modulate AKAP10 biological activities related to AKAP10 binding to PKA, AKAP10 localization in the mitochondria, binding to other signaling enzymes and phosphorylation by PKA.

Regarding the claims to primers, probes, antisense nucleic acid molecules, kits, solid supports, microarrays and isolated nucleic acids comprising at least 20 nucleotides of SEQ ID NO:3 set forth in claims 11-18, 47-50, 69-71, 75 and 76, it is respectfully submitted that it is well-established that these nucleic acids are useful in nucleic acid detection methods for detecting the particular allelic variant present at position 2073 of SEQ ID NO:1 or SEQ ID NO:3 of the nucleic acid of claim 1. Notwithstanding the well-established utility plainly evident to those of skill in the art, the specification clearly asserts such a utilities for these nucleic acids, for example, at pages 46-68, including:

> **1. Nucleic acid detection methods**
>
> Generally, these methods are based in sequence-specific polynucleotides, oligonucleotides, probes and primers. Any method known to those of skill in the art for detecting a specific nucleotide within a nucleic acid sequence or for determining the identity of a specific nucleotide in a nucleic acid sequence is applicable to the methods of determining the presence or absence of an allelic variant of the AKAP10 gene. Such methods include, but are not limited to, techniques utilizing nucleic acid hybridization of sequence-specific probes, nucleic acid sequencing, selective amplification, analysis of restriction enzyme digests of the nucleic acid, cleavage of mismatched heteroduplexes of nucleic acid and probe, alterations of electrophoretic mobility, primer specific extension, oligonucleotide ligation assay and single-stranded conformation polymorphism analysis. In particular, primer extension reactions that specifically terminate by incorporating a dideoxynucleotide are useful for detection. Several such general nucleic acid detection assays are known (see, *e.g.*,U.S. Patent No. 6,030,778). ...
>
> **2. Primers, probes and antisense nucleic acid molecules**
>
> Primers refer to nucleic acids which are capable of specifically hybridizing to a nucleic acid sequence which is adjacent to a polymorphic region of interest or to a polymorphic region and are extended. A primer can be used alone in a detection method, or a primer can be used together with at least one other primer or probe in a detection method. Primers can also be used to amplify at least a portion of a nucleic acid. For amplifying at least a portion of a nucleic acid, a forward primer (*i.e.*, 5' primer) and a reverse primer (*i.e.*, 3' primer) will preferably be used. Forward and reverse primers hybridize to complementary stands of a double stranded nucleic acid, such that upon extension from each primer, a double stranded nucleic acid is amplified.
>
> Probes refer to nucleic acids which hybridize to the region of interest and which are not further extended. For example, a probe is a nucleic acid which hybridizes adjacent to or at a polymorphic region of an AKAP gene and which by hybridization or absence of hybridization to the DNA of a subject will be indicative of the identity of the allelic variant of the polymorphic region of the gene.

Accordingly, it is respectfully submitted that the subject matter of claims 11-18, 47-50, 69-71, 75 and 76, is at useful for making, amplifying, detecting or producing a protein from, the nucleic acid of claim 1 encoding an AKAP10

variant protein. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

THE REJECTION OF CLAIMS 1-8, 11-20, 44-53, 69-71 and 75 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1-8, 11-20, 44-53, 69-71 and 75 are also rejected under 35 U.S.C. §112, first paragraph because the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth in the §101 rejection, and therefore one skilled in the art clearly would not know how to use the claimed invention. This rejection is respectfully traversed.

It is respectfully submitted that the specification teaches a specific, substantial and credible utility as set forth above in the response to the §101 rejection, the specification teaches the skilled artisan how to use the claimed invention, under 35 U.S.C. §112. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

THE WRITTEN DESCRIPTION REJECTION OF CLAIMS 6-8, 11-18, 44, 47-50, 69-71 and 75 UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 6-8, 11-18, 44, 47-50, 69-71 and 75 are rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

RELEVANT LAW

The purpose behind the written description requirement is to ensure that the patent applicant had possession of the claimed subject mater at the time of filing of the application. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). The manner in which the specification meets the requirement is not material; it may be met by either an express or an implicit disclosure.

The written description requirement is distinct from and not coterminous with the enablement requirement:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563-64, 19 USPQ2d at 1117 (emphasis in original).

Accordingly, a specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, *i.e.*, whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ.2d 1111, 1117 (Fed. Cir. 1991).

An objective standard for determining compliance with the written description requirement is "does the description clearly allow persons of skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ.2d 1614, 1618 (Fed. Cir.1989).

The Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the application a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976); *See also Ex parte Sorenson*, 3 USPQ2d 1462, 1463 (Bd. Pat.App. & Inter. 1987). By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); and *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973).

ANALYSIS

With respect to claims 6-8 and 15-18, the Examiner alleges that the instant specification has not described a representative number of members within the very large genus of any isolated nucleic acid which comprises 14, 30 or 50 contiguous nucleotides of SEQ ID NO:3 that includes 5 contiguous nucleotides from positions 2069-2077 of SEQ ID NO:3. It is respectfully submitted that those of skill in the art would readily understand that as long as the stated minimum fragment lengths of nucleotides derived from SEQ ID NO:3 contain 5 contiguous nucleotides from positions 2069-2077 of SEQ ID NO:3, numerous sequences readily can be combined with these fragments such that a multiplicity of sequences comprising these fragments are described.

The Examiner next urges that:

> The genus of nucleic acids comprising at least 14, 30 or 50 contiguous nucleotides from SEQ ID NO:3 encompasses splice variants of AKAP10-5, polymorphic sequences of AKAP10-5, a full length gene which contains the fragment and homologous sequences which have not been described.

It is respectfully submitted that the claims do not require splice variants of AKAP10-5, polymorphic sequences of AKAP10-5, a full length gene which contains the fragment, and homologous sequences. Thus, although these additional features may be present with the claimed subject matter, because these features are not required by claims 6-8 and 15-18, a written description of these features is likewise not required.

With respect to claims 11-14, 47-50 and 69-71 directed to a primer, probe or antisense molecule, the Examiner alleges that "the corresponding sequence does not require any particular similarity or identity with SEQ ID NO:1 or 3." Claim 11 as amended, requires that the primer, probe or antisense nucleic acid molecule, comprising a sequence of at least 16 nucleotides that specifically hybridizes **under high stringency conditions corresponding to 0.1 x SSPE, 0.1% SDS, 65°C** adjacent to, or at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID No. 1 or SEQ ID No. 3, or

the complement thereof, of an AKAP10 allele. It is well-known to those of skill in the art that the "high stringency conditions" require that the nucleotide sequences of the claimed primer, probe or antisense molecules correlate to a particular structural similarity or identity to SEQ ID NO:1 or 3 that is about 90% or more similar or identical. Thus, in view of the specification, it is respectfully submitted that those of skill in the art would readily understand that applicant was in possession of a group of molecules, other than an exact 16-mer derived from SEQ ID NO:1 or 3, that are at least 90% identical to SEQ ID NO:1 or 3, and that hybridize to reference sequences SEQ ID NOs:1 or 3 under "high stringency conditions."

Applicant respectfully disagrees with the Examiner's various concerns over the term "corresponding," such as set forth in the Examiner's assertion that:

> As defined by the specification, a nucleic acid which "corresponds" to the nucleic acid may be of different length, such that the sequences are aligned and then the position that lines up with 2073 is identified (page 38-39). This does not require any particular sequence flanking the nucleotide "other than A."...Thus, the "corresponding" sequence does not require any particular similarity or identity with SEQ ID NO:1 or 3.

First, it is respectfully submitted that any sequence of at least 16 nucleotides that specifically hybridizes adjacent to or at a polymorphic region spanning a particular nucleotide on a reference sequence, necessarily requires particular similarity or identity with that particular reference sequence. Moreover, the specification explicitly teaches:

> As used herein, "at a position corresponding to" refers to a position of interest (*i.e.*, base number or residue number) in a nucleic acid molecule or protein relative to the position in another reference nucleic acid molecule or protein. **Corresponding positions can be determined by comparing and aligning sequences to maximize the number of matching nucleotides or residues, for example, such that identity between the sequences is greater than 95%, preferably greater than 96%, more preferably gr ater than**

> **97%, even more preferably great r than 98% and most pref rably greater than 99%. The position of interest is then given the number assigned in the reference nucleic acid molecule.** For example, it is shown herein that a particular polymorphism in AKAP-10 occurs at nucleotide 2073 of SEQ ID No. 1. **To identify the corresponding nucleotide in another allele or isolate, the sequences are aligned and then the position that lines up with 2073 is identified. Since various alleles may be of different length, the position designate 2073 may not be nucleotide 2073, but instead is at a position that "corresponds" to the position in the reference sequence.**

It is respectfully submitted that in view of the specification, those of skill in the art would clearly understand that a "corresponding position" requires that the sequences flanking the corresponding position are, for example, at least 95% identical to the reference sequence.

Regarding claim 44, Applicant respectfully disagrees with the Examiner's assertion that:

> The specification has described a single human AKAP10 variant protein, namely a substitution at amino acid position 646 of SEQ ID NO:2. The specification does not particular[sic] provide any additional variant proteins that exhibit a biological activity of the variant protein. The specification fails to provide any biological activity information for the variant protein to constitute a function, therefore, determining whether the portion exhibits biological activity has not been described.

Claim 44 is directed to "[a] cell, comprising heterologous nucleic acid that encodes a human AKAP10 variant protein or portion that exhibits a biological activity of the full length variant protein, wherein the AKAP10 variant protein or portion thereof comprises valine at a position corresponding to the position of amino acid residue 646 of SEQ ID NO: 2." The claims require that the human AKAP10 variant protein comprises Val at residue 646 of SEQ ID NO:2, or comprises a fragment of SEQ ID NO:2 having Val at the position corresponding to residue 646 of SEQ ID NO:2. Thus, the full length variant protein, or the claimed fragments encoded by the heterologous nucleic acid, must contain a Val

at a position corresponding to residue 646 of SEQ ID NO:2. The specification provides adequate basis for numerous nucleic acids encoding fragments of AKAP10 having Val at residue 646 of SEQ ID NO:2. See, for example, the paragraph bridging page 78 and 79, which teaches:

> A. Expression of AKAP Protein
>
> The isolated nucleic acid encoding a full-length polymorphic human AKAP10 protein, **or a portion thereof, such as a fragment containing the site of the polymorphism [e.g., Val at residue 646 of SEQ ID NO:2]**, may be introduced into a vector for transfer into host cells. Fragments of the polymorphic human AKAP10 proteins can be produced by those skilled in the art, without undue experimentation, by eliminating portions of the coding sequence from the isolated nucleic acids encoding the full-length proteins. (emphasis added)

Likewise the specification provides adequate basis for a biological activity of the full length protein or fragments thereof having Val at the position corresponding to residue 646 of SEQ ID NO:2. See, for example, page 42, lines 10-21, which teaches:

> Polymorphisms of AKAP genes that alter gene expression, regulation, protein structure and/or protein function are more likely to have a significant effect on the regulation of enzyme (particularly PKA) activity, cellular transduction of signals and responses thereto and on the basic functioning of cells than polymorphisms that do not alter gene and/or protein function. Included in the polymorphic AKAPs provided herein are human AKAP10 proteins containing differing amino acid residues at position number 646 of SEQ. ID. No. 2.
>
> **Amino acid 646 of the human AKAP10 protein (SEQ. ID. NO: 2) is located in the carboxy-terminal region of the protein within a segment that participates in the binding of R-subunits of PKAs. This segment includes the carboxy-terminal 40 amino acids.**

In view of the specification, those of skill in the art would readily understand that fragments of human AKAP10 protein containing residue 646 of SEQ ID NO:2 would have the biological activity of binding to PKA or to an R-subunit within PKA. Accordingly, it is respectfully submitted that the skilled artisan

would clearly recognize that Applicant was in possession of cells comprising heterologous nucleic acids encoding fragmented portions of AKAP10 that exhibit a biological activity of the full length variant protein, such as PKA binding, RI subunit binding and/or RII subunit binding. In addition, it is respectfully submitted that the specification, at pages 87-89 clearly sets forth that the activity of an AKAP10 protein or portion thereof can be determined by examining signal transduction in the cell or by examining binding of AKAP10 protein or portion thereof to protein kinase A (or the RI and/or RII subunits thereof) or by examining cellular phosphorylation.

The Examiner also urges that:

> Furthermore, the claim encompasses additional mutations, splice variants and transitions which have not been described in the instant specification.

It is respectfully submitted that the claims do not require additional mutations, splice variants and/or transitions. Thus, although these additional features may be present with the claimed subject matter, because these features are not required by claim 44, a written description of these features is likewise not required.

Regarding claim 75, Applicant respectfully disagrees with the Examiner's assertion that:

> Claim 75 is drawn broadly to a primer **consisting essentially of** a nucleotide selected from SEQ ID NO:8, 15, 19 and 20. The nucleic acid reads on any oligonucleotide which comprises SEQ ID NO:8, 15, 29 and 20 which vary in length from 17-20 nucleotides. As discussed above, the partial structure embedded within a larger sequence is not representative of the entire genus, as exemplified by the art rejections below. (emphasis added)

It is well-known that the phrase "consisting essentially of" is not the same as "comprising." The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method

steps. See, *e.g.*, *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Whereas, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

Claim 75 is directed to a "primer" consisting essentially of nucleotide sequences selected from the group consisting of SEQ ID NO: 8, SEQ ID NO: 15, SEQ ID NO: 19 and SEQ ID NO: 20. Thus, the claimed primers can only include additional material that does not materially affect the basic and novel characteristics of the claimed primers.

With respect to primers, the instant specification teaches, at page 61, lines 2-13, that:

> Primers refer to nucleic acids which are **capable of specifically hybridizing to a nucleic acid sequence which is adjacent to a polymorphic region of interest or to a polymorphic region and are extended.** A primer can be used alone in a detection method, or a primer can be used together with at least one other primer or probe in a detection method. Primers can also be used to amplify at least a portion of a nucleic acid. For amplifying at least a portion of a nucleic acid, a forward primer (*i.e.*, 5' primer) and a reverse primer (*i.e.*, 3' primer) will preferably be used. Forward and reverse primers hybridize to complementary stands of a double stranded nucleic acid, such that upon extension from each primer, a double stranded nucleic acid is amplified. (emphasis added)

Thus, a basic and novel characteristic of the claimed primers is the capability of hybridizing adjacent to the polymorphic region of interest for subsequent nucleotide extension from the 3' end of the primer. It is respectfully submitted that Applicant's specification, at page 62, lines 1-10, provides basis for primers that can contain additional material that does not materially affect the basic and novel characteristic of the claimed primer:

> Primers and probes (RNA, DNA (single-stranded or double-stranded), PNA and their analogs) described herein **may be labeled**

> **with any detectable reporter or signal moiety** including, but not limited to radioisotopes, enzymes, antigens, antibodies, spectrophotometric reagents, chemiluminescent reagents, fluorescent and any other light producing chemicals. Additionally, these [primers and] probes **may be modified without changing the substance of their purpose by terminal addition of nucleotides designed to incorporate restriction sites or other useful sequences,** proteins, signal generating ligands such as acridinium esters, and/or paramagnetic particles. (emphasis added)

Thus, in view of Applicant's specification, those of skill in the art would clearly recognize the Applicant was in possession of primers consisting essentially of SEQ ID NOs:8, 15, 19 and 20, that could be modified by labelling with a detectable reporter or signal moiety, or modified by incorporating a restriction site, as is well-known in the art.

Reconsideration and withdrawal of this rejection is therefore respectfully requested.

THE REJECTION OF CLAIMS 6-8, 11-18 AND 47-50 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 6-8, 11-18 and 47-50 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleges that the claims are indefinite with respect to the recitation of the phrases "at least 14 or 16 contiguous nucleotides" and "a sequence of nucleotides that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID NO:1 or 3 of an AKAP10 alelle." This rejection is respectfully traversed.

RELEVANT LAW

The purpose of 35 U.S.C. §112, second paragraph, is to permit those who would endeavor, in future enterprise, to approach the area circumscribed by the claims of a patent and to determine the metes and bound of protection so that they can evaluate the possibility of infringement with a reasonable degree of certainty. *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (CCPA

1970). When one skilled in the art would understand all of the language in the claims when read in light of the specification, a claim is not indefinite. *Rosemount Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547, 221 USPQ 1, 7 (Fed. Cir. 1984), *Caterpillar Tractor Co. v. Berco, S.P.A.*, 714 F.2d 1110, 1116, 219 USPQ 185, 188 (Fed. Cir. 1983).

Moreover, the claims are not to be read in a vacuum; the limitations therein are to be interpreted in light of the specification giving them their broadest reasonable interpretation. *In re Marosi, Stabenow, Schwarzmann, Lank*, 710 F.2d 799, 218 USPQ 289, 292 (Fed. Cir. 1983). 35 U.S.C. §112, second paragraph requires only reasonable precision in delineating the bounds of the claimed invention. The claim language is satisfactory if it reasonably apprises those of skill in the art of the bounds of the claimed invention and is as precise as the subject matter permits. *Shatterproof Glass Corp. v. Libby-Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), *cert dismissed*, 106 S. Ct. 340 (1985):

> [i]t is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter (*Bendix Corp. v. United States*, 600 F.2d 1364, 1369, 220 Ct. Cl. 507, 514, 204 USPQ 617, 621 (1979).

ANALYSIS

With respect to the recitation of the phrase "at least 14 or 16 contiguous nucleotides," it is respectfully submitted that the Examiner's concern has been rendered moot by the amendment to claims 6 and 15 herein, which clarifies that the claim is drawn to at least 16 contiguous nucleotides.

With respect to the Examiner's concern regarding claims 11-18 and 47-50, claim 11 has been amended herein to require in pertinent part, "a sequence of nucleotides that specifically hybridizes (under high stringency conditions) adjacent to, or at a polymorphic region spanning, a position corresponding to position 2073 of SEQ ID No. 1 or SEQ ID No. 3, or the complement thereof, of an AKAP10 alelle." It respectfully submitted that the amendment to claim 11

makes it clear to those of skill in the art that the primer, probe or antisense nucleic acid molecule hybridizes either adjacent to a position corresponding to nucleotide 2073 of SEQ ID NO:1 or SEQ ID NO:3, or hybridizes at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID NO:1 or SEQ ID NO:3. The position corresponding to position 2073 of SEQ ID NO:1 or SEQ ID NO:3, is within an AKAP10 allele.

Reconsideration and withdrawal of this rejection is therefore respectfully requested.

THE REJECTIONS UNDER 35 U.S.C. §102

Relevant law

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir, 1990), *In re Bond*, 15 USPQ 1566 (Fed. Cir. 1990), *Soundscriber Corp. v. U.S.* 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. See, also, *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir.), *cert. denied*, 110 S.Ct. 154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention". *In re Lang*, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Moreover it is incumbent on Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. *Lindemann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

Further, the reference must describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. Prior art does not anticipate a thing or process unless it is enabling; an anticipatory publication must describe the claimed invention with sufficient clarity and specificity so that one skilled in the relevant art could practice the subject matter of the patent without assistance from the patent claimed to have been anticipated *Columbia Broadcasting System v. Sylvania Elec. Products, Inc.*,

415 F.2d 719, 735, 162 USPQ 577 (1st Cir.1968) *cert. denied*, 396 U.S. 1061, 164 USPQ 321 (1970).

"Before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention." *Titanium Metals Corp. v Mossinghoff*, 603 F.Supp. 87,0, 225 USPQ 673 (1984) quoting *In re Application of Le Grice*, 49 CCPA 1124, 301 F.2d 9333.

Claim 6

Claim 6 is rejected under 35 U.S.C. §102(e) as allegedly anticipated by United States patents 6,262,334 to Endege *et al.*, and 6,294,328 to Fleischmann *et al.* Endege *et al.* is alleged to disclose a nucleic acid comprising 15 contiguous nucleotides of SEQ ID NO:3, namely positions 2073-2087. Fleischmann *et al.* is alleged to teach a nucleic acid comprising 15 contiguous nucleotides of SEQ ID NO:3, namely positions 2072-2086. This rejection is respectfully traversed.

Analysis

Claim 6, as amended, differs from the disclosure in the '334 and '328 patents by requiring an isolated nucleic acid molecule "comprising at least 16 contiguous nucleotides of SEQ ID NO:3." As acknowledged by the Examiner, neither the '334 nor the '328 patents discloses an isolated nucleic acid molecule comprising at least 16 contiguous nucleotides of SEQ ID NO:3, as required by claim 6. Accordingly, the '334 and the '328 patents do not anticipate claim 6.

Claims 11-14 and 69-71

Claims 11-14 and 69-71 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by United States patent 5,474,796 to Brennan. The Examiner alleges that "[s]ince the claims are broadly drawn to generic claims referring to any nucleic acid, of any length and of any sequence, Brennan,

having disclosed every 10 mer anticipates the claims. This rejection is respectfully traversed.

Analysis

Claims 11 and 69, as amended, differ from Brennan *et al.* by requiring a sequence of nucleic acids of at least 16 nucleotides in length. Because Brennan only discloses 10 mer nucleotides, Brennan does not anticipate these claims since it does not disclose every element as claimed.

Claim 75

Claim 75 is rejected under 35 U.S.C. §102(b) as allegedly anticipated by Birren *et al.* (Genbank #AC005730; 10/98). The Examiner alleges that Birren et al. "teaches a nucleic acid clone from chromosome 17 which comprises all 18 nucleotides of SEQ ID NO:20. Nucleotides 1-18 of SEQ ID NO:20 are identical to positions 129,582-129,599 of the chromosome 17 nucleic acid. Therefore, Birren teaches a nucleic acid comprising SEQ ID NO:20 as required by the instant claim." This rejection is respectfully traversed.

Analysis

It is well-known that the phrase "consisting essentially of" is not the same as "comprising." The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, *e.g.*, *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Whereas, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

Claim 75 is directed to a "primer" consisting essentially of nucleotide sequences selected from the group consisting of SEQ ID NO: 8, SEQ ID NO: 15, SEQ ID NO: 19 and SEQ ID NO: 20.

With respect to primers, the instant specification teaches, at page 61, lines 2-13, that:

> Primers refer to nucleic acids which are **capable of specifically hybridizing to a nucleic acid sequence which is adjacent to a polymorphic region of interest or to a polymorphic region and are extended.** A primer can be used alone in a detection method, or a primer can be used together with at least one other primer or probe in a detection method. Primers can also be used to amplify at least a portion of a nucleic acid. For amplifying at least a portion of a nucleic acid, a forward primer (*i.e.*, 5' primer) and a reverse primer (*i.e.*, 3' primer) will preferably be used. Forward and reverse primers hybridize to complementary stands of a double stranded nucleic acid, such that upon extension from each primer, a double stranded nucleic acid is amplified. (emphasis added)

Thus, a basic and novel characteristic of the claimed primers is the capability of hybridizing adjacent to the polymorphic region of interest for subsequent nucleotide extension from the 3' end of the primer. It is respectfully submitted that the additional 162,020 nucleotides of the Birren Genbank sequence (of which at least 30,000 nucleotides are downstream of the 3' end of the claimed primer) would indeed materially affect the basic and novel characteristic(s) of the claimed primer consisting essentially of SEQ ID NO:20, because the additional 30,000 nucleotides at the 3' end of the claimed primer would materially affect the primers ability to hybridize adjacent to the polymorphic region of interest for subsequent nucleotide extension from the 3' end of the primer. Accordingly, it is respectfully submitted that the Birren Genbank sequence is outside the scope of the claimed primer consisting essentially of SEQ ID NO:20, and therefor does not anticipate Applicant's claimed primer.

Claim 75

Claim 75 is rejected under 35 U.S.C. §102(b) as allegedly anticipated by Adams *et al.* (Genbank #AA331406; 4/97). The Examiner alleges that Adams teaches a nucleic acid that comprises all 19 nucleotides of SEQ ID NO:19. Nucleotides 1-19 of SEQ ID NO:19 are identical to positions 45-27 of the human

nucleic acid. Therefore, Adams allegedly teaches a nucleic acid comprising SEQ ID NO:19 as required by the instant claim. This rejection is respectfully traversed.

Analysis

Claim 75 is directed to a "primer" consisting essentially of nucleotide sequences selected from the group consisting of SEQ ID NO: 8, SEQ ID NO: 15, SEQ ID NO: 19 and SEQ ID NO: 20.

With respect to primers, the instant specification teaches, at page 61, lines 2-13, that:

> Primers refer to nucleic acids which are **capable of specifically hybridizing to a nucleic acid sequence which is adjacent to a polymorphic region of interest or to a polymorphic region and are extended.** A primer can be used alone in a detection method, or a primer can be used together with at least one other primer or probe in a detection method. Primers can also be used to amplify at least a portion of a nucleic acid. For amplifying at least a portion of a nucleic acid, a forward primer (*i.e.*, 5' primer) and a reverse primer (*i.e.*, 3' primer) will preferably be used. Forward and reverse primers hybridize to complementary stands of a double stranded nucleic acid, such that upon extension from each primer, a double stranded nucleic acid is amplified. (emphasis added)

Thus, a basic and novel characteristic of the claimed primers is the capability of hybridizing adjacent to the polymorphic region of interest for subsequent nucleotide extension from the 3' end of the primer. It is respectfully submitted that the additional 159 nucleotides of the Adams Genbank sequence #AA331406 (of which 26 nucleotides are downstream of the 3' end of the claimed primer) would indeed materially affect the basic and novel characteristic(s) of the claimed primer consisting essentially of SEQ ID NO:19, because the additional 26 nucleotides at the 3' end of the claimed primer would materially affect the primers ability to hybridize adjacent to the polymorphic region of interest for subsequent nucleotide extension from the 3' end of the primer. Accordingly, it is respectfully submitted that the Adams Genbank

sequence is outside the scope of the claimed primer consisting essentially of SEQ ID NO:19, and therefor does not anticipate Applicant's claimed primer.

Claim 75

Claim 75 is rejected under 35 U.S.C. §102(b) as allegedly anticipated by Adams *et al.* (Genbank #AA349877; 4/97). The Examiner alleges that Adams teaches a nucleic acid that comprises all 18 nucleotides of SEQ ID NO:15. Nucleotides 1-18 of SEQ ID NO:15 are identical to positions 198-181 of the human nucleic acid. Therefore, Adams allegedly teaches a nucleic acid comprising SEQ ID NO:15 as required by the instant claim. This rejection is respectfully traversed.

Analysis

Claim 75 is directed to a "primer" consisting essentially of nucleotide sequences selected from the group consisting of SEQ ID NO: 8, SEQ ID NO: 15, SEQ ID NO: 19 and SEQ ID NO: 20.

With respect to primers, the instant specification teaches, at page 61, lines 2-13, that:

> Primers refer to nucleic acids which are **capable of specifically hybridizing to a nucleic acid sequence which is adjacent to a polymorphic region of interest or to a polymorphic region and are extended.** A primer can be used alone in a detection method, or a primer can be used together with at least one other primer or probe in a detection method. Primers can also be used to amplify at least a portion of a nucleic acid. For amplifying at least a portion of a nucleic acid, a forward primer (*i.e.*, 5' primer) and a reverse primer (*i.e.*, 3' primer) will preferably be used. Forward and reverse primers hybridize to complementary stands of a double stranded nucleic acid, such that upon extension from each primer, a double stranded nucleic acid is amplified. (emphasis added)

Thus, a basic and novel characteristic of the claimed primers is the capability of hybridizing adjacent to the polymorphic region of interest for subsequent nucleotide extension from the 3' end of the primer. It is respectfully submitted that the additional 258 nucleotides of the Adams Genbank sequence

#AA349877 (of which 180 nucleotides are downstream of the 3' end of the claimed primer) would indeed materially affect the basic and novel characteristic(s) of the claimed primer consisting essentially of SEQ ID NO:19, because the additional 180 nucleotides at the 3' end of the claimed primer would materially affect the primers ability to hybridize adjacent to the polymorphic region of interest for subsequent nucleotide extension from the 3' end of the primer. Accordingly, it is respectfully submitted that the Adams Genbank sequence is outside the scope of the claimed primer consisting essentially of SEQ ID NO:19, and therefor does not anticipate Applicant's claimed primer.

THE REJECTION OF CLAIMS 47 AND 48 UNDER 35 U.S.C. §103

Claims 47-48 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Brennan '796 in view of Ahern, July 1995, *The Scientist, 9(15)*:20. The Examiner alleges that Brennan teaches a microarray comprising every possible 10-mer. The Examiner asserts that "[s]ince the claims are broadly drawn to generic claims referring to any nucleic acid, of any length and of any sequence, Brennan, having taught every 10 mer **anticipates** the claims. It is further stated that Brennan does not specifically teach packaging the nucleic acid in a kit.

It is next alleged that Ahern teaches reagent kits (that) offer scientists good return on investment, because the kits save time and money and already come prepared. The Examiner asserts that it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Brennan with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. The ordinarily skilled artisan would have been motivated to have packaged the primers, probes and reagents of Brennan into a kit, as taught by Ahern for the express purpose of saving time and money.

This rejection is respectfully traversed.

RELEVANT LAW

In order to set forth a *prima facie* case of obviousness under 35 U.S.C. § 103: (1) there must be some teaching, suggestion or incentive supporting the combination of cited references to produce the claimed invention (*ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)) and (2) the combination of the cited references must actually teach or suggest the claimed subject matter. Further, that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. *Ex parte Gerlach*, 212 USPQ 471 (Bd. APP. 1980). Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art" *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981), but it cannot be established by combining the teachings of the prior art to produce the claimed subject matter, absent some teaching or suggestion supporting the combination (*ACS Hosp. Systems, Inc. v. Montefiore Hosp.* 732 F.2d 1572, 1577. 221 USPQ 929, 933 (Fed. Cir. 1984)). "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher" *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

The prior art must provide a motivation whereby one of ordinary skill in the art would have been led to do that which the applicant has done. *Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). In addition, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 USPQ 1783 (Fed. Cir. 1992).

THE CLAIMS

The kits of claims 47 and 48, as amended, require a kit, comprising:

a first primer or probe of claim 11; and

a second primer or probe that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to positions selected from the group consisting of position 83587 of SEQ ID NO 13 or 17, position 129600 of SEQ ID NO 14 or 17, and position 156,277 of SEQ ID NO 18 or 17 of an AKAP10 allele or the complement thereof. Claim 11, as amended, requires a primer, probe or antisense nucleic acid molecule, comprising a sequence of at least 16 nucleotides that specifically hybridizes under high stringency conditions corresponding to 0.1 x SSPE, 0.1% SDS, at 65°C adjacent to, or at a polymorphic region spanning, a position corresponding to position 2073 of SEQ ID No. 1 or SEQ ID No. 3, or the complement thereof, of an AKAP10 allele.

THE CITED REFERENCES

Brennan '796

The Brennan patent is generally directed to methods for making an array of functionalized nucleotide binding sites on a support surface. Brennan only teaches sequences for an array of trimer oligonucleotides and one 10-mer DNA fragment representing the target fragment that binds to different trimers within the array (see Figure 1A). In addition, Brennan certainly does not teach or suggest any portion of SEQ ID NOs:1 or 3, nor any 16-mer oligonucleotides, as required by the claims. Thus, Brennan clearly does not teach or suggest the particular combinations of first and second primers or probes having the requisite characteristics as claimed.

Ahern

The Ahern reference certainly does not cure the deficiency of Brennan. Ahern is merely directed to general benefits of purchasing kits rather than making the individual reagent components of a kit individually. For example, as

set forth by the Examiner, Ahern merely teaches that reagent kits offer scientists good return on investment, because the kits save time and money and already come prepared.

There would have been no motivation to have combined Brennan '796 with Ahern

Brennan teaches nothing regarding SEQ ID NOs:1 or 3, as required by the claims. Moreover, Brennan does not teach or suggest any information regarding oligonucleotides greater than 10-mers. Ahern certainly does not cure these deficiencies of Brennan. Ahern merely discloses the general benefits of kits in research. Accordingly, there clearly would have been no motivation to combine the disclosures of Brennan and Ahern. As set forth below, even when combined, these references do not result in the claimed kits.

The combination of Brennan '796 with Ahern does not result in the instantly claimed kits

As set forth above, because Brennan only discloses 10-mer oligonucleotides, Brennan does not teach or suggest any 16-mer primers or probes, as required by Applicant's claims. Assuming *arguendo* that there would have been motivation to have combined the teachings of Brennan with Ahern, the combination would not result in a kit with the specified claimed primers. The instant claims are directed to a kit that contains a first primer or probe of at least 16 nucleotides in length and a second primer or probe that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to positions selected from the group consisting of position 83587 of SEQ ID NO 13 or 17, position 129600 of SEQ ID NO 14 or 17, and position 156,277 of SEQ ID NO 18 or 17 of an AKAP10 allele or the complement thereof. Neither Brennan nor Ahern, singly or in combination, teaches or suggests such primers or probes. Therefore the combination cannot suggest a kit containing the primers.

Reconsideration and withdrawal of this rejection is therefore respectfully requested.

Respectfully submitted,
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